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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,672	06/17/1999	MATTHIAS G. VON HERRATH	SCRIP1100	7934

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EXAMINER
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SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/04/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/336,672**

Applicant(s)  
**Von Herrath**

Examiner  
**William Sandals**

Art Unit  
**1636**



-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 27, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40-68 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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**DETAILED ACTION**

***Response to Arguments***

1. Claims 1-3, 5, 7-14, 16-24 and 26-39 have been canceled and new claims 40-68 have been submitted. Applicant's arguments with respect to claims 1-3, 5, 7-14, 16-24 and 26-39 have been considered as they apply to new claims 40-68, but are moot in view of the new ground(s) of rejection.

***Drawings***

2. New formal drawings are required in this application because recent changes to the MPEP, section 608.02(c) no longer allow deferral of submission of drawings pursuant to notification. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

***Claim Objections***

3. Claim 51 is objected to because of the following informalities: at line 2 before "nucleic acid" the article "the" is required for proper grammatical construction. Appropriate correction is required.

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***Response to Amendment***

4. The Declaration filed in Paper No. 22, on January 15, 2002 under 37 CFR 1.131 is sufficient to overcome the Liu et al. reference.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 47-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 47 recites at line 1, "treating a condition associated with autoimmune diabetes".

There is no definition of what is meant by the term "treating a condition associated with autoimmune diabetes" in the claims or specification, and the term is not an art defined term.

Therefore, one of ordinary skill in the art would not know the metes and bounds of the term "treating a condition associated with autoimmune diabetes", and the claim is therefore vague and indefinite.

8. Claims 47, 54 and 62 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as

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being "selected from the group consisting of A, B and C." See Ex parte Markush , 1925 C.D. 126 (Comm'r Pat. 1925).

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 40, 41, 43-45, 47, 50, 51, 53, 54, 57, 58, 60, 62, 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokui et al.

Tokui et al. teach (see the abstract) an immunomodulating composition for treating autoimmune diabetes (type-1) comprising an expression plasmid encoding GAD and IL-4 in a pharmaceutically acceptable carrier. The immunomodulating composition is used in a method of treating autoimmune diabetes (type-1) by expressing the plasmid in a NOD mouse diabetes model system.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

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art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 40-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokui et al.

in view of US 5,891, 435.

The claims are drawn to an immunomodulating composition for treating autoimmune diabetes (type-1) comprising an expression vector encoding insulin B or GAD and encoding a cytokine IL-4 or IL-10 in a pharmaceutically acceptable carrier. The immunomodulating composition is used in a method of treating autoimmune diabetes (type-1) by expressing the vector in an individual which may be a NOD mouse or a human. The expression construct is under the control of a regulatory element.

Tokui et al. taught the invention as described above in the rejection under 35 USC 102.

Tokui et al. did not teach the use of an expression plasmid encoding insulin B, nor that the method may be used in a human, nor the various promoters of claims 46, 52, 59 or 67.

US 5,891,435 taught (see especially the abstract, summary, column 6, column 7, lines 48-65, column 9, lines 29-53, and example 4) an immunomodulating composition for treating autoimmune diabetes (type-1) comprising an expression vector encoding insulin B or GAD in a pharmaceutically acceptable carrier. The immunomodulating composition is used in a method of treating autoimmune diabetes (type-1) by expressing the vector in an individual which may be a NOD mouse or a human. US 5,891,435 taught that interleukins were known to suppress autoimmune diabetes. The expression construct is under the control of a regulatory element (various).

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It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Tokui et al. with US 5,891,435 to produce the instant invention because Tokui et al. and US 5,891,435 were both taught the use of an expression vector encoding GAD to treat autoimmune diabetes.

One of ordinary skill in the art would have been motivated to combine the teachings of Tokui et al. with US 5,891,435 to produce the instant invention because Tokui et al. and US 5,891,435 both taught the desirable and useful expression vector encoding GAD to treat autoimmune diabetes. US 5,891,435 taught the useful and desirable treatment of autoimmune diabetes may be practiced with an expression vector which encodes either GAD or insulin B, and that the method may be practiced in a NOD mouse or a human. US 5,891,435 made note of the fact that interleukins were known to suppress autoimmune diabetes. Tokui et al. taught the desirable and useful expression vector encoding GAD to treat autoimmune diabetes where the expression vector also expresses IL-4, where interleukins are known to suppress autoimmune diabetes. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Tokui et al. and US 5,891,435.

IL-4 and IL-10 are listed as equivalents in the instant specification. Therefore, the limitation of IL-10 is obvious over the teaching of IL-4.

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***Conclusion***

13. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

June 2, 2002

A handwritten signature in black ink, appearing to read "William Sandals", is written over the printed name and date.